

B.Braun Medical - Request for Information JeannaR Henry

to:

david.lauer

11/18/2011 10:14 AM

Cc:

henry.jeannar Hide Details

From: JeannaR Henry/R3/USEPA/US

To: david.lauer@bbraun.com

Cc: henry.jeannar@epa.gov

Good Morning Mr. Lauer:

Thank you for getting back to me. Per your voicemail message, here are the follow-up questions I have regarding the May 2, 2011 Environmental Indicator (EI) Inspection that was conducted at B. Braun Medical, Inc. (PAD982679169) by Michael Baker Jr., Inc. (Baker) on behalf of EPA. Once you've had a chance to review the following questions, please let me know if you'd like to have a call to go over any or all of the questions in more detail. I would like to receive the requested information by Monday, November 28, 2011 so that I can complete both the Human Health and Groundwater EIs for this Facility.

Requested Information:

- 1. Please verify that the information contained in the following paragraph is factually correct. If any of the information below is incorrect, please provide the appropriate edits.
- B. Braun Medical, Inc. (B. Braun) is a privately-owned health care company that provides healthcare products, services and educational programs that enhance the care and safety of patients and healthcare professionals in the fields of drug delivery, IV therapy, pain control, clinical nutrition, dialysis and vascular intervention. B. Braun's products and services are used in hospitals, outpatient surgery centers and in the home care setting. B. Braun's facility (herein after referred to as "B. Braun," "Facility," or "Site") located at 901 Marcon Boulevard in Hanover Township, Lehigh County, Pennsylvania, manufactures, prepares and sterilizes plastic disposable medical devices, such as valves, adapters, piercing devices, stopcocks, infusion pumps and systems, syringes, cannulae, regional anesthesia, balloon catheters, fluid administration systems, interventional products, and safety products.
- 2. The EI Report states that the Facility's original 285,000 square foot building was constructed in 1985, with an additional 75,000 square foot building constructed in 2009. Is the 75,000 square foot addition connected directly to the original building? How does B. Braun refer to each of the buildings (i.e. Main Building).

- 3. With respect to the Facility's elementary neutralization unit (ENU), please answer the following:
 - (A) Which building (original or addition) houses the Facility's ENU?
 - (B) When was the Facility's ENU installed?
 - (C) When did the Facility's ENU begin operation?
- 4. According to the EI Report, the Facility's former Hazardous Waste Accumulation Area (HW Accumulation Area) was located on the east side of the Facility building, just outside of the main building. Please answer the following questions regarding the Facility's former HW Accumulation Area:
 - (A) Please provide the dates (i.e., beginning/ending) of operation for the Facility's former HW Accumulation Area.
 - (B) Please provide a detailed description of the former HW Accumulation Area and how it was constructed (e.g., fenced, covered, concrete or gravel base, etc.)
 - (C) Please identify the types of waste and provide the EPA Hazardous Waste Code associated with the hazardous wastes stored in the former HW Accumulation Area.
- 5. The EI Report states that the Facility's current hazardous waste accumulation area is located on the north end of the property adjacent to the building. Please identify which building the current HW Accumulation Area is located adjacent to. Also, please identify the types of waste and provide the EPA Hazardous Waste Code associated with the hazardous wastes stored in the Facility's current HW Accumulation Area.
- 6. With respect to the Facility's use of ethylene oxide, please answer the following:
 - (A) State the name of the room that is used to store raw material drums of ethylene oxide. Is this room also used for the storage of "empty" (used) ethylene oxide drums? If not, please identify the room where used drums of ethylene oxide are stored.
 - (B) Does the Facility manage the used drums of ethylene oxide as a hazardous waste (U115)? If so, please provide a detailed narrative that explains how the Facility handles and manages its used drums of ethylene oxide. In your description, please include labeling and dating of drums, how drums are moved from area to area, employee training required for handling used drums of ethylene oxide, manifesting (provide an example copy), and information regarding the entity that receives the used drums of ethylene oxide from B.
 - (C) If the Facility is not managing the used drums of ethylene oxide as a hazardous waste,
 please provide a detailed narrative that explains the Facility's rationale for not managing such
 drums as hazardous waste. If the drums are being managed as non-hazardous in
 accordance with a RCRA exemption or exclusion, please identify the exemption or
 exclusion. In addition, submit any and all supporting documentation (e.g., waste
 determination, EPA guidance letter, PADEP determination letter).
- 7. Please answer the following questions regarding Tank 001, emergency catch basin UST:
 - (A) Please identify where Tank 001 is located at the Facility.
 - (B) Has the Facility performed a hazardous waste determination on the liquid that is removed from Tank 001 routinely? If so, please state whether or not the liquid was determined to be hazardous (include EPA HW Code) and submit any and all supporting waste determination documentation (e.g., waste profile, sampling data).
 - (C) Is the liquid removed from Tank 001 at the same time the 3,000-gallon above-ground storage tank (AST) associated with the Facility's ENU is emptied? If so, are the contents of Tank 001 and the 3,000-gallon AST co-mingled for off-site shipment?

Again, please let me know if you would like additional clarification on any of the questions above. Thanks!

Jeanna R. Henry, Environmental Scientist U.S. Environmental Protection Agency, Region III Office of Pennsylvania Remediation

Phone: 215/814-2820 Fax: 215/814-3113



B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109

Telephone: 610-596-2934 Fax: 610-266-5702

November 23, 2011

Subject: EPA Request for Information

- 1. Please verify that the information contained in the following paragraph is factually correct. If any of the information below is incorrect, please provide the appropriate edits.
 - B. Braun Medical, Inc. (B. Braun) is a privately-owned health care company that provides healthcare products, services and educational programs that enhance the care and safety of patients and healthcare professionals in the fields of drug delivery, IV therapy, pain control, clinical nutrition, dialysis and vascular intervention. B. Braun's products and services are used in hospitals, outpatient surgery centers and in the home care setting. B. Braun's facility (herein after referred to as "B. Braun," "Facility," or "Site") located at 901 Marcon Boulevard in Hanover Township, Lehigh County, Pennsylvania, manufactures, prepares and sterilizes plastic disposable medical devices, such as valves, adapters, piercing devices, stopcocks, infusion pumps and systems, syringes, cannulae, regional anesthesia, balloon catheters, fluid administration systems, interventional products, and safety products.
 - All of the above information is factually correct and accurate.
- 2. The EI Report states that the Facility's original 285,000 square foot building was constructed in 1985, with an additional 75,000 square foot building constructed in 2009. Is the 75,000 square foot addition connected directly to the original building? How does B. Braun refer to each of the buildings (i.e. Main Building).
 - The addition that was added in 2009 is attached to the original structure. This new construction is referred to as the Specialty Product Manufacturing (SPM) building, it is also considered Phase IV.
- 3. With respect to the Facility's elementary neutralization unit (ENU), please answer the following:
 - (A) Which building (original or addition) houses the Facility's ENU?
 - (B) When was the Facility's ENU installed?
 - (C) When did the Facility's ENU begin operation?
 - a) The part of the facility that houses the Elementary Neutralization Unit (ENU) is referred to as the Deoxx Room. The ENU is located in the

Deoxx Room and it is part of the original structure. The ENU is surrounded by a dike to prevent any releases.

b) The ENU was installed in 1985.

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- c) The ENU was also put in operation in 1985.
- 4. According to the EI Report, the Facility's former Hazardous Waste Accumulation Area (HW Accumulation Area) was located on the east side of the Facility building, just outside of the main building. Please answer the following questions regarding the Facility's former HW Accumulation Area:
 - (A) Please provide the dates (i.e., beginning/ending) of operation for the Facility's former HW Accumulation Area.
 - (B) Please provide a detailed description of the former HW Accumulation Area and how it was constructed (e.g., fenced, covered, concrete or gravel base, etc.)
 - (C) Please identify the types of waste and provide the EPA Hazardous Waste Code associated with the hazardous wastes stored in the former HW Accumulation Area.
- The former Hazardous Waste Accumulation Area was located on the Southeast part of the facility off of the main building.
 - a) The dates of operation of the former hazardous waste accumulation area were from 1989 to 2002.
 - b) This structure was a hazardous material shed with a designed secondary containment to prevent any discharges into the environment. This shed is also designed to meet all Local, State, and Federal specifications. The shed was in a fenced in area to prevent unauthorized entrance into this area.
 - c) The types of waste and their EPA hazardous waste codes are as follows:
 - D001, D002 Methylene Chloride Waste
 - P042 Epinephrine Waste
 - D001 Mineral Spirits, Hydraulic Oil Waste
 - F002, D001, F003 Isopropyl, Methylene Chloride Waste
 - D001 Aerosol Waste.
 - D002 Sodium Hydroxide
 - D001 Paint Related Waste
 - D002 Corrosive Liquid Waste
 - D001, D035 Flammable Liquid Waste
- 5. The EI Report states that the Facility's current hazardous waste accumulation area is located on the north end of the property adjacent to the building. Please identify which building the current HW Accumulation Area is located adjacent to. Also, please identify the types of waste and provide the EPA Hazardous Waste Code associated with the hazardous wastes stored in the Facility's current HW Accumulation Area.

- The current hazardous waste accumulation area is on the Northeast Side of the building and is adjacent to the main building. This structure is a hazardous material shed with a designed secondary containment to prevent any discharges into the environment. This shed is also designed to meet all Local, State, and Federal specifications. This area houses the following types of waste:
 - D001, D002 Methylene Chloride Waste
 - P042 Epinephrine Waste
 - D001 Mineral Spirits, Hydraulic Oil Waste
 - F002, D001, F003 Isopropyl, Methylene Chloride Waste
 - D001 Aerosol Waste
 - D002 Sodium Hydroxide
 - D001 Paint Related Waste
 - D002 Corrosive Liquid Waste
 - D001, D035 Flammable Liquid Waste
- 6. With respect to the Facility's use of ethylene oxide, please answer the following:
 - (A) State the name of the room that is used to store raw material drums of ethylene oxide. Is this room also used for the storage of "empty" (used) ethylene oxide drums? If not, please identify the room where used drums of ethylene oxide are stored.
 - (B) Does the Facility manage the used drums of ethylene oxide as a hazardous waste (U115)? If so, please provide a detailed narrative that explains how the Facility handles and manages its used drums of ethylene oxide. In your description, please include labeling and dating of drums, how drums are moved from area to area, employee training required for handling used drums of ethylene oxide, manifesting (provide an example copy), and information regarding the entity that receives the used drums of ethylene oxide from B. Braun.
 - (C) If the Facility is not managing the used drums of ethylene oxide as a hazardous waste, please provide a detailed narrative that explains the Facility's rationale for not managing such drums as hazardous waste. If the drums are being managed as non-hazardous in accordance with a RCRA exemption or exclusion, please identify the exemption or exclusion. In addition, submit any and all supporting documentation (e.g., waste determination, EPA guidance letter, PADEP determination letter).
 - (a) The room that is used to store the raw or full drums of Ethylene Oxide is referred to as the Ethylene Oxide Room or Gas Room. This room is an internal confined room located inside the confines of the facility. When the drums are emptied of Ethylene Oxide they are moved to a secured dock area. This dock area is fenced and locked to prevent unauthorized entrance to the dock area.
 - (b) The facility does not manage the used or empty drums as a hazardous waste (U115).
 - (c) The empty drums are handled as a hazardous material. As per Bob Bogart of ARC/Balchem the empty drums are handled as follows, "The

used drums are returned to the ARC Specialty Products filling site as a Hazardous Material with the proper shipping name of (RQ Residue Last Contained: UN 1040 Ethylene Oxide, 2.3, (Poison Gas), (2.1), (Flammable Gas), Hazard Zone D, Poison-Inhalation Hazard)". When received the drums are purged of remaining product and collected. Once enough material is collected, the material is sent to our manufacturing facility in Missouri as a Hazardous Material. In this facility, the ethylene oxide is used as a raw material in manufacturing as part of its normal operation.

- 7. Please answer the following questions regarding Tank 001, emergency catch basin UST:
 - (A) Please identify where Tank 001 is located at the Facility.
 - (B) Has the Facility performed a hazardous waste determination on the liquid that is removed from Tank 001 routinely? If so, please state whether or not the liquid was determined to be hazardous (include EPA HW Code) and submit any and all supporting waste determination documentation (e.g., waste profile, sampling data).
 - (C) Is the liquid removed from Tank 001 at the same time the 3,000-gallon above-ground storage tank (AST) associated with the Facility's ENU is emptied? If so, are the contents of Tank 001 and the 3,000-gallon AST comingled for off-site shipment?
 - (a) Tank 001 (Underground Storage Tank UST) is located on the Northwest side of the facility. This area is also protect by a locked fenced area to prevent any unauthorized personnel from accessing this area.
 - (b) The contents (Ethylene Glycol) stored in Tank 001 does not ship as a hazardous waste, it is shipped as a hazardous material.
 - (c) During a pick up the contents of tank 001 (UST) are removed at the same time as the 3,000 gal Above Storage Tank (AST). The contents of the UST and the AST are comingled for offsite reclamation (recycled).

I trust that the enclosed information will meet your expectations. If I can be of further assistance, or if you require additional information, please do not hesitate to contact me directly at 610-596-2934.

Thank you,

Chip Marshall

Environmental, Health & Safety Specialist

B BRAUN

April 30, 1997

Mr. Robert K. Lewis
Department of Environmental Protection (DEP)
Facility Section Supervisor, Northeast Regional Office
2 Public Square
Wilkes Barre, PA 18711–0790

Dear Mr. Lewis,

It has been brought to B. Braun's attention by the local DEP office: that B. Braun's required to apply for a Permit By Rule because of the neutralization process of Ethylene Glycol (25 PA CODE 265.433—Neutralization Treatment Units). A description of the neuralization process is herein, per your request. The neutralization waste is hazardous (40 CFR 261.10) because of the corrositivity of the mixture (20%-ethylene glycol, 80% water). Before neutralization, the mixture has a pH of .5-1.0. The ethylene glycol/water mixture is then treated with sodium hydroxide to establish and maintain a pH of 7. After neutralization, the ethylene glycol/water mixture is non-hazardous and taken off-site by American Chemical Exchange (ACE).

B. Braun steps undertaken in the compliance with 25 PA CODE 265.433—Neutralization Treatment Units: B. Braun Medical has a NPDES (National Pollutant Discharge Elimination System) permit with the Borough of Catasauqua (265.433 (2) and has an EPA ID number with the EPA (264.11). The neutralization unit is located within the building which requires card access to the building and card access to the area of the neutralization unit (264.14). A preventative maintenance program is maintained for the entire sterilization area and retained at the facility (264.15). All operating records are kept at the facility (264.73). B. Braun will file a biennial report by March 1, 1998, if as a large quantity generator B. Braun generates more than 2, 200 lbs. of hazardous waste in any one month of the reporting year (264.75). Additional reports are filed, if necessary (264.77). The criteria for Chapter 264, Subchapters C & D; and Chapter 265, Subchapter Q, have been complied with as stated in the regulation.

Attached please find a schematic of the neutralization process and a detailed description of the neutralization process and its purpose. I am looking forward to your response regarding acknowledgement of B. Braun's neutralization treatment process. If you have any question regarding this matter, please feel free to contact myself at (610) 691–5400 or Steve Stancick, Sterilization Manager, at (610) 266-0500.

Sincerely,

Lisa M. Millington

Environmental Affairs Coordinator

cc:

H. Morrison

Dr. L Lucas

D. Calek

S. Stancick

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Charlie B. Braun Medical Inc. PAL 49254

824 Twelfth Avenue

PO Box 4027

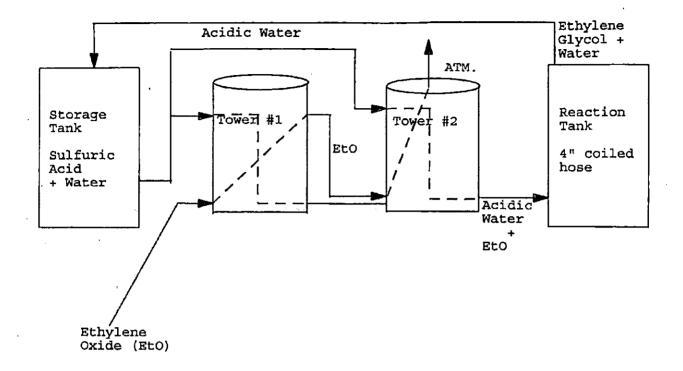
Bethlehem, PA 18018-0027

WASTE MANAGEMENT
COUNTY: LEALGH.

MAY 12 1997

FACILITY: B Brann funit by Rule
FILE CODE: Application funit by Rule

DEOXX SCRUBBER SYSTEM



Ethylene Oxide Gas Stream enters bottom of Tower #1.
Acidic water enters top of Towers 1/2.
Entrapment occurs when Ethylene Oxide mixes with acidic water.
Added efficiency occurs thru Tower #2.
Final EtO/Acidic Water mixture goes to Reaction Tank.
Mixing of EtO/Acidic Water converts mixture to ethylene glycol + water.
Ethylene Glycol Mixture is recirculated back to the Storage tank.
Storage Tank Liquid is reused until tank is full or concentration reaches 50%.

AGREEMENT

This Agreement between American Chemical Exchange Company, Inc. and Burron Medical (Generator) sets forth the terms and conditions under which American Chemical Exchange agrees to pay the Generator for removal of the ethylene glycol mixture (Mixture) produced as a by-product of Generator's ethylene oxide sterilization emissions control systems.

1. Notifications: All notifications and correspondence in regards to the terms and conditions of this Agreement will be made to:

> American Chemical Exchange Co., Inc. 9847 Hibiscus Court Alta Loma, California 91701

Attn: Robert Somerman

909-484-2542

DIONNE Hill

FAY: 909-987-9798

Generator:

Burron Medical 904 Postal Road Allentown, PA-18103

Attn: Steve Stancick

610-226-0500

All notifications and changes to this Agreement will be made in writing.

2 Charge or Payment Terms: 66/647

Allentown, PA 2,500 gallons

Current 12/96

0/gallon

Pricing: If the market price of Ethylene Glycol increases, the payment to the Generator will be increased. If the market price decreases, a similar adjustment will be made. Pricing will be calculated from spot market prices and will be adjusted as a percentage of that price. Notification of price changes will be made in writing.

Demurrage Charges: Generator will be responsible for all Demurrage charges resulting from any Generator related occurrence that delays or prevents the loading of the mixture 2 hours after the tanker truck has arrived. The Demurrage charges will be \$80.00 per hour.

Cancellation Charges: The Generator will be responsible for any cancellation charges resulting from any Generator occurrence that would prevent a tanker truck from arriving on the day scheduled. Cancellation charges will total \$ 225.00 per occurrence.

Additional Charges: Because Mixture is a by-product of a manufacturing process, American Chemical Exchange acknowledges that the specifications of the Mixture, including the pH and the concentration of ethylene glycol of the Mixture will vary from lot to lot. However, sufficient testing has been conducted to determine that the total ethylene glycol (mono, di & tri-) concentration will average between 10% and 60% of the Mixture with this concentration.

For Concentrations less than 20% glycol, freight plus a flat fee of \$500.00 will be charged. The pH of the Mixture prior to neutralization will normally be less than 1.5. Most state and federal transportation regulations require that the pH be greater than 2.0 but not greater than 11.5. Therefore, to include a safety factor, Generator will neutralize the Mixture to a pH of approximately 7.0.

Generator will not ship any Mixture that for any reason has become contaminated with any substance not normally produced by the emission control or neutralization process. Upon arrival to the shipping point if the material is determined to be contaminated with a foreign substance not associated with emission control or neutralization processes, the material will be sent back to the Generator freight collect, for both directions. In order to avoid guesswork and additional costs it is strongly recommended that samples be prepared and sent to Gabriel Labs. 114221 N. Elston Ave., Chicago, IL 60622. Attention: Donna Panek. Please label sample material with appropriate information, name of Generator, address and date. Please also note that results should be sent to American Chemical Exchange.

- 3. Compliance: Both parties will comply with all applicable laws, statutes, rules and regulations concerning use, handling and transportation. According to CFR guidelines parts 261,2 (e) & (f).
- 4. Material Safety Data Sheet: Upon request, American Chemical Exchange will provide Generator with a Material Safety Data Sheet (MSDS) for each lot of Mixture.
- 5. <u>Disclaimer of Warranties:</u> Generator makes no warranty, either expressed or implied, including any warranty of fitness for a particular or intended purpose of merchantability.
- 6. Hold Harmless: American Chemical Exchange will indemnify and hold Generator harmless from and against any and all claims, actions, charges, suites, liabilities, losses, costs and expenses, including reasonable attomeys' fees, resulting from the purchase, use or transportation of the Mixture or of any product made from the Mixture composition as defined in Additional Charges in Section 2.
- 7. Insurance: All transporters and processors contracted by American-Chemical Exchange to haul and use the Mixture maintain vehicle and liability insurance coverage in an amount no less than \$1,000,000 per occurrence and Workmen's Compensation as required by statute.

- 8. Facilities, Personnel & Equipment: On days of shipments, Generator's facilities and personnel will assist driver in pumping the Mixture into the tank truck. The tank trucks we dispatch will provide 20-40 feet of hose and a pump American Chemical Exchange will provide adequate hose for hook up from Generator equipment to transfer.
- 9. Terms & Termination: This Agreement shall remain in effect until terminated by either party upon 60 days prior written notice.

AMERICAN CHEMICAL EXCHANGE CO., INC.								
By: // Someonian	Date: 1/6/96							
,,	•							
BURRON MEDICAL								
By: Steve Stancick	Date: 1/6/96							

Addendum to Agreement

- 1. Use: The material from DeOxx will be used in the manufacture of:
 - a. Automobile Coolants
 - b. Herbicides
 - c. Fire Extinguishing Fluids

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MATAWAN, N.J. • (908) 566-3000

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